

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE BIOPURE CORPORATION
SECURITIES LITIGATION**

)
) **Civil Action No. 03-CV-12628-NG**
)
)

**REPLY MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT RONALD F. RICHARDS' MOTION TO
DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT**

**ATTORNEY FOR DEFENDANT
RONALD F. RICHARDS**

Christopher F. Robertson (BBO # 642094)
SEYFARTH SHAW LLP
World Trade Center East
Two Seaport Lane
Suite 300
Boston, MA 02210-2028
Telephone: (617) 946-4800
Telecopier: (617) 946-4801

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PRELIMINARY STATEMENT

In their opposition brief, the plaintiffs rely heavily upon the fact that certain individual defendants in this case were issued Wells notices by the Securities and Exchange Commission. In doing so however, the plaintiffs have completely undermined and defeated any inference, never mind a strong inference, of scienter on the part of defendant Ronald F. Richards, who was not issued such a notice. Likewise, by emphasizing that certain individual defendants sold shares of Biopure stock during the class period, plaintiffs have defeated any inference of scienter as to Richards, who did not sell any stock. These allegations, advanced to support the statutory pleading requirements of the PSLRA, were the plaintiffs' choice, and they cannot now have it both ways. The simple and unchallenged facts are that (i) despite conducting a comprehensive year-long investigation and obtaining unfettered access to Biopure documents and witnesses, the SEC has not seen fit to allege even negligent conduct by Richards; (ii) Richards did not sell a single share of Biopure stock during the class period and himself suffered a financial loss when the Company's stock price fell; and (iii) there are no allegations of accounting problems or false financial reporting by Biopure or Richards, the Company's former Chief Financial Officer.

Moreover, the only statement directly attributed to Richards in the entirety of the Amended Complaint confirms only that Biopure made no guarantees whatsoever that its products would ever be approved by the FDA. Unlike the cases cited by the plaintiffs, Biopure's public filings made clear that the FDA approval process was extremely risky and had no guarantee of success. Contrary to the plaintiffs' argument, which attempts to gloss over this critical issue, a close reading of the challenged statements themselves reveals that there is absolutely no statement of "expectation" of FDA approval, but rather repeated disclosure of the significant risks to that approval ever being obtained. "The securities laws do not require that investors be treated like children ... investors know that the stock market is a risky business and

that when a company's officer makes predictions, [he is] not making guarantees.” In re Duane Reade Inc. Sec. Litig., No. 02 CIV. 6478 NRB, 2003 WL 22801416, at *6 (S.D.N.Y. Nov. 25, 2003), aff'd, Nadoff v. Duane Reade, Inc., 107 Fed.Appx. 250 (2d Cir., Aug. 17, 2004) (dismissing complaint). Absent any such guarantee by Richards or some specific allegation supporting a strong inference of scienter, the amended complaint as to him must be dismissed.

ARGUMENT

I. THE PLAINTIFFS' ALLEGATIONS DEFEAT ANY INFERENCE OF SCIENTER AS TO DEFENDANT RONALD F. RICHARDS

Plaintiffs recognize that they must allege specific facts supporting a *strong* inference of scienter as to each defendant individually, including Richards. Opp. Br. at 20. Plaintiffs also concede that the SEC has not issued a Wells notice to Richards, and that Richards did not sell any shares of Biopure stock during the class period. The Court cannot ignore these facts, which undermine and defeat any inference of scienter. Nonetheless, the plaintiffs ask this Court to conclude that they have met their stringent pleading obligations under the PSLRA because of what the SEC “presumably could” do in the future.¹ Opp. Br. at 51 n. 18. Such reasoning would turn the PSLRA’s statutory pleading requirement on its head. The plaintiffs -- as masters of their complaint -- chose to emphasize the SEC Wells process as the key fact supporting their claim that each individual defendant acted with fraudulent intent. They cannot in the same breath ignore the fact that the SEC determined to exclude Richards from that process and expect this

¹ The plaintiffs argue in a footnote to their brief that their reliance on the SEC Wells process should have no bearing on their claims against Richards, because the SEC “might” decide to issue a Wells notice to Richards sometime in the future. There are several responses to this argument. First, the SEC has now been investigating this matter for over a year and no Wells notice has been issued to Richards. Second, attempting to support a *strong* inference of fraudulent conduct on what the SEC has elected not to do but “might” do in the future would eviscerate the pleading requirements of the PSLRA. It is the plaintiffs’ burden to advance allegations that support a strong inference of fraudulent intent now, not some unspecified and speculative time in the future. Where those allegations in reality support exactly the opposite inference, the Court cannot ignore them.

Court to still draw a *strong* inference of scienter as to him. That is particularly so when the SEC's jurisdiction includes not only fraudulent, but also negligent, conduct. See Gaines v. Guidant Corp., No. 1:03CV00892–SEB-WTL, 2004 WL 2538374, at *16 (S.D. Ind. Nov. 8, 2004) (“Accepting all the factual allegations in the Complaint as true and drawing all reasonable inferences from these facts in favor of the Plaintiffs, we are stopped short of a finding of a strong inference of scienter based on numerous facts contained in the Complaint that undermine an inference of scienter, *which we cannot and must not ignore.*”) (emphasis added).

Likewise, the absence of any stock trading by Richards in connection with the alleged fraud further undermines and defeats any inference of scienter. In Guerra v. Teradyne Inc., No CIV. A. 01-11789-NG, 2004 WL 1467065, at *28 (D. Mass. Jan. 16, 2004), for example, the Court recognized that the lack of stock sales and the substantial losses by individual defendants “undermines any inference of scienter.” (quoting Maldonado v. Dominguez, 137 F.3d 1, 12 n. 9 (1st Cir. 1998)). Similarly, in Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353, 369 (5th Cir. 2004), the Court noted that the lack of stock sales by the defendants around the time of the allegedly misleading statements undermined any inference of scienter. See In re Copper Mountain Sec. Litig., 311 F.Supp.2d 857, 875 (N.D. Cal. 2004) (where defendant retained more shares than he sold, such facts will defeat any inference of scienter).

Attempting to overcome these obvious pleading deficiencies, the plaintiffs trot out the oft-repeated mantra that the Court must still draw all reasonable factual inferences in favor of the plaintiffs. Opp. Br. at 20. That argument misses the crucial issue, namely that drawing those inferences in the plaintiffs' favor as to defendant Richards affirmatively defeats any inference – never mind a strong inference – of scienter. See, e.g., In re Read-Rite Corp. Sec. Litig., No. C-03-03148 RMW, 2004 WL 2125883, at *3 (N.D. Cal. Sept. 22, 2004) (court must consider all

inferences from complaint, including inferences unfavorable to the plaintiffs); In re Metawave Communications Corp. Sec. Litig., 298 F.Supp.2d 1056 (W.D. Wash. 2003) (“If the Court could not draw inferences unfavorable to the plaintiff in determining scienter, the PSLRA’s strong inference requirement would be eviscerated, and Congress’s basic purpose in enacting the PSLRA would be thwarted”). Stated another way by the Fifth Circuit, a district court need not indulge in “irrational inferences” in connection with evaluating a securities fraud complaint. Melder v. Morris, 27 F.3d 1097, 1103 (5th Cir. 1994).

Recognizing the lack of any Wells notice from the SEC and absence of stock trading by Richards, the plaintiffs attempt to end-run these negative inferences by citing to his position within the company, as well as his internal controls and financial statement certification obligations under the Sarbanes-Oxley Act. As a preliminary matter, it is well-settled that “allegations of a highly-efficient reporting system do not independently provide a factual basis for inferring the defendants’ knowledge.” Carney v. Cambridge Tech. Partners, Inc., 135 F.Supp.2d 235, 255 (D. Mass. 2001), quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1224 n. 38 (1st Cir. 1996). See also Guerra v. Teradyne Inc., 2004 WL 1467065, at *25 (alleging the existence of efficient internal reporting systems “will not do much to increase the particularity of a securities fraud pleading”). Likewise, it is well settled that knowledge cannot be imputed to an individual defendant simply by virtue of the defendant’s position within the company. See Orton v. Parametric Tech. Corp., 344 F.Supp.2d 290, 306 (D. Mass. 2004) (“Nor does a vague assertion that a defendant must have known about the fraud by virtue of his position of authority suffice to prove a strong inference of scienter”); In re Galileo Corp. Shareholders Litig., 127 F.Supp.2d 251, 261 (D. Mass. 2001) (allegation that defendants “must have known” certain facts “solely by virtue of their positions” is insufficient).

Moreover, Richards' position at Biopure and his execution of these certifications were well known to the SEC in connection with its investigation, and the SEC concluded that it should not assert that Richards had engaged in even negligent conduct. Finally, as the CFO of Biopure, Richards' responsibility was to assure that the Company's financial controls were sufficient to assure compliance with Generally Accepted Accounting Principals and Generally Accepted Auditing Standards.² As the plaintiffs concede, there is no allegation whatsoever of *any* violations in this regard, nor is there any allegation that any deficiency in internal financial controls resulted in the preparation of any misleading financial statement or false statement of account. See In re Michaels Stores, Inc. Sec. Litig., No. CIV. A. 3:03-CV-0246, 2004 WL 2851782, at *12 n. 11 (N.D. Tex. Dec. 10, 2004) (rejecting plaintiffs' citation to a signed certification as a basis for establishing scienter).

In short, the plaintiffs continue to fail to cite to any specific document or meeting in which Richards was specifically informed of any information inconsistent with any statement directly attributed to him. See In re Boston Tech. Inc. Sec. Litig., 8 F. Supp. 2d 43, 57 (D. Mass. 1998) (dismissing complaint where plaintiff failed to cite to specific meetings or reports). In Irvine v. Imclone Systems, Inc., 02 Civ. 109 (RO), 2003 U.S. Dist. LEXIS 9342, *5-6 (S.D.N.Y. June 4, 2003), for example, a case cited by the plaintiffs, the Court dismissed fraud charges

² Both before and after the passage of the Sarbanes-Oxley Act, companies were required to certify in management letters to their auditors that adequate internal financial controls existed. These standards, promulgated by the AICPA, provided the framework for the Sarbanes-Oxley certification provisions. Notably, the standards recognize that the creation of and implementation of an internal control structure, "no matter how well designed and operated, can provide only reasonable assurance" of achievement of all objectives. See Codification of Statements on Auditing Standards, AT Section 501 (2004) (discussing the definition of internal control and the limitations of any internal control structure). Here, where there is no allegation that the control environment failed in any way related to financial statement preparation and reporting, it is not reasonable to impute knowledge to the company's CFO of all company information, especially information unrelated to financial controls and reporting. See Imclone, 2003 U.S. Dist. LEXIS 9342, at *6 (refusing to impute knowledge of technical and scientific information to general counsel and vice president of sales and marketing).

against Imclone's General Counsel and Vice President of Marketing and Sales, where there were no specific facts alleged demonstrating that they "had any reason to know that the technical and scientific information included was anything other than true at the time they were made." The same is true here. There are absolutely no specific facts alleged, such as a meeting or report, demonstrating that Richards had any reason to know that any statement in any of Biopure's public filings was untrue when made, to the extent such statements are actionable at all. See Zouras v. Hallman, No. Civ. 03-240-SM, 2004 WL 2191034, at *7 (D.N.H. Sept. 30, 2004) ("Plaintiff's complaint falls short in alleging factual knowledge on the part of [the CFO] that would have made any of the statements attributed to them false or misleading"); Carney v. Cambridge Tech. Partners, Inc., 135 F.Supp.2d at 255 (lack of citation to specific meeting or report failed to raise strong inference of scienter). In light of the lack of any Wells notice to Richards, the lack of any stock sales, and the lack of citation to any specific contradictory meeting or report, the plaintiffs are left without a single specific fact supporting any inference of scienter, and a host of facts affirmatively undermining such an inference. The Court need go no further in dismissing the amended complaint as to Richards.

II. PLAINTIFFS HAVE NOT IDENTIFIED ANY ACTIONABLE MISSTATEMENTS BY RICHARDS

Plaintiffs do not dispute that a securities fraud complaint must be evaluated on a statement-by-statement basis. Zouras v. Hallman, 2004 WL 2191034, at *7. Moreover, in doing so "specific statements must be attributed to specific individuals." In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 960 (D. Md. 1995). See In re Michaels Stores, 2004 WL 2851782, at *11 ("a plaintiff must plead specific factual allegations linking a particular defendant to the particular statement or omission at issue"); D.E. & J. Limited Partnership v. Conaway, 284 F.Supp.2d 719, 730 (E.D. Mich. 2003) (complaint must identify each allegedly false or

misleading statement made by each defendant individually; it is improper to attribute *all* statements to *all* defendants); In re Stratus Computer, Inc. Sec. Litig., No. Civ. A. 89-2075-Z, 1992 WL 73555, at *4 (D. Mass. March 27, 1992) (“Rule 9(b) requires specification of which defendants are performing what acts”).³ Thus, even if the Plaintiffs were able to provide specific facts supporting a strong inference of Richards’ intent to defraud shareholders – which they clearly have not – they would still need to establish that the specific statements attributable to Richards are somehow actionable. This the plaintiffs cannot do.

The *only* statements directly attributable to Richards are those contained in Biopure’s public filings during the class period, including certain quarterly reports filed with the SEC, and certain shelf registration statements. As to these filings, the Plaintiffs have identified the same statements as allegedly misleading, which are simply not actionable as a matter of law. None of these statements make any guarantees whatsoever regarding FDA approval, and, taken as a whole expressly caution that obtaining such approval is highly risky. The subject statements, therefore, do not go nearly as far as those rejected by Judge Stearns in In re PLC Systems, Inc. Sec. Litig., 41 F.Supp.2d 106 (D. Mass. 1999). In that case, unlike here, the defendants made statements targeted directly at an “expectation” of FDA approval by year-end. Nonetheless, even these statements, not worded as guarantees, were not actionable. Id. at 117-18, citing Medimmune, 873 F. Supp. at 964.

³ The plaintiffs do not challenge Richards’ argument that they must attribute specific statements to him individually and support their allegations of scienter as to him individually as to each such statement. Instead of challenging this argument, the plaintiffs continue to lump all of the defendants together in their opposition and apparently seek to attribute each and every alleged statement to each and every defendant, including Richards. As set forth in detail in Richards’ moving brief, this form of pleading is unacceptable. See, e.g., In re Michaels Stores, 2004 WL 2851782, at *12 (dismissing certain individual defendants, including the CFO, where plaintiff failed to link specific statements to specific individuals); Medimmune, 873 F. Supp. at 964 (it is “impermissible” to attribute all statements to all defendants).

A close look at the statements analyzed in the other cases cited by the plaintiffs leads to the same conclusion. For example, in In re Transkaryotic Therapies, Inc. Sec. Litig., 319 F.Supp.2d 152 (D. Mass. 2004), a case heavily relied upon by the plaintiffs, Judge Zobel identified a number of statements that “plainly” fell within the safe harbor provisions. These statements – which go well beyond any statements attributed to Richards – included all of TKT’s plans for the future, as well as “pronouncements about the possibility of FDA approval” and the statement that there was a “very real possibility” of 2002 approval. Id. at 161 n. 11. See In re Viropharma, Inc. Sec. Litig., C.A. Master File No. 02-1627, 2003 U.S. Dist. LEXIS 5623, at *21 (E.D. Pa. April 3, 2003) (in case cited by plaintiffs, statement that the company believed its drug was “on a strong track to approval,” not actionable because “investors should not rely on a company’s prediction about the future actions of independent government agencies”). To the contrary, Judge Zobel concluded that the statement by the Company’s CEO that FDA approval “remains a when not if proposition” was not protected. This holding is not surprising, given that such a statement is plainly worded as a guarantee. See In re Sepracor, Inc. Sec. Litig., 308 F.Supp.2d 20, 32 (D. Mass. 2004) (finding actionable statements that company was “confident” in FDA approval and “expected” FDA approval within a specified time frame).

Here, contrary to the argument advanced by the plaintiffs, there are no statements attributed to Richards which speak to any “expectation” or “guarantee” of FDA approval.⁴ Rather, the statements at issue speak to the significant risks in obtaining such approval and make no assurances of any kind that such approval is imminent or on any particular schedule. As

⁴ Apparently recognizing this critical distinction, plaintiffs repeatedly characterize statements made by the defendants as statements of “expectation” more akin to guarantees. See Opp. Br. at 44 (“defendants’ statements that they expect FDA approval”). A reading of the actual statements cited by the plaintiffs in this regard, however, makes clear that none of them contain any such language, and, when read in context, make clear that FDA approval is anything but guaranteed.

recognized by the Court in Medimmune, “the key word is guarantee. Mere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable.” 873 F. Supp. at 964. See PLC Systems, Inc., 41 F.Supp.2d at 118 (expressions of hope not worded as guarantees not actionable).

In In re Columbia Laboratories, Inc. Sec. Litig., 144 F.Supp.2d 1362 (S.D. Fla. 2001), for example, the Court analyzed whether statements by the defendants that they “believed” Columbia would receive FDA approval, and would receive such approval within six months, were actionable as a matter of law. As a preliminary matter, the Court noted that “[i]n determining whether a statement is forward looking, the Court must read the statements not in isolation but in the context of the entire document.” Id. at 1368. Notwithstanding this mandate, the plaintiffs surgically remove certain statements from Biopure’s public filings and present them to the Court out of context. Moreover, the Court held that the determination that a statement was a nonactionable statement of belief ended the inquiry. That is, once the Court determines that in the overall context of the statement, it is immaterial and nonactionable, the facts regarding how that statement came to be made are “irrelevant to the analysis.” Id. Thus, the plaintiffs’ belabored attempts to resurrect an otherwise nonactionable statement with unsupported allegations that Richards “must have known” the “belief” advanced in the statement was unreasonable, cannot save the statement from dismissal. See Galileo Corp., 127 F.Supp.2d at 261 (allegations that defendants “must have known” certain facts insufficient to save dismissal).

In addition, the plaintiffs’ characterization of the numerous and substantive risk disclosures in the company’s public filings as mere “boilerplate” must also fail. Contrary to the argument advanced by plaintiffs, Biopure included over nine pages of specific and detailed risk disclosures, including the very real possibility that the company would never obtain FDA

approval, the company would fail, and investors would lose money. These disclosures, which repeatedly inform investors of the risks inherent in an investment in Biopure, are more than adequate. See In re Seachange Int'l, Inc. Sec. Litig., No. Civ. A. 02-12116-DPW, 2004 WL 240317, at *5 (D. Mass. Feb. 6, 2004) (“Given the abundance of cautionary language and the forward-looking tone of the ‘Risk Factors’ section, I find that the statements plaintiffs identify within the section – regarding demand for products, competitive position and revenue growth – were not materially misleading because they are protected under the safe harbor provisions of the PSLRA”).

III. THERE IS NO OTHER BASIS FOR A CLAIM AGAINST RICHARDS

In his moving brief, Richards provided substantial authority holding that there could be no liability for simply “participating” in alleged misstatements or omissions by others, under the Supreme Court’s decision in Central Bank v. First Interstate Bank, 511 U.S. 164, 176-77 (1994). See, e.g., Shapiro v. Cantor, 123 F.3d 717, 720 (2d Cir. 1997) (defendant must actually make a misleading statement and cannot be liable for mere participation). In Copland v. Grumet, 88 F.Supp.2d 326, 332 (D.N.J. 1999), for example, the court refused to impose liability upon two officers of the corporate defendant alleged to have “participated” in the fraudulent statements of others. The court held that the officers’ “participation in this process cannot be the equivalent of *making* the false statements themselves.” See, e.g., Wright v. Ernst & Young LLP, 152 F.3d 169, 175 (2d Cir. 1998) (no liability for mere “participation” in alleged fraudulent statement; statement must be actually made by the defendant); In re Rent-Way Securities Litig., 209 F.Supp.2d 493, 502 (W.D. Pa. 2002) (varying levels of “participation” in another’s misstatement “do not give rise to primary liability after *Central Bank*”); In re Kendall Square Research Corp. Sec. Litig., 868 F. Supp. 26, 28 (D. Mass. 1994) (alleged participation, including review and

approval of statement, did not create liability). The plaintiffs have provided no answer to this authority, instead simply inserting a footnote without citation stating that Richards' alleged "participation" is sufficient. Opp. Br. at 38 n. 16. It is not, and as a result, their allegations of "participation" by Richards in statements of others must be dismissed.

Likewise, as recognized in Medimmune, the plaintiffs cannot evade the requirement of identifying specific statements by Richards with blanket allegations of control person liability. 873 F. Supp. at 964 ("specific allegations of control and culpable conduct are required"). Rather, as set forth in Richards' moving brief, the plaintiffs must allege specific facts demonstrating actual knowledge of the fraudulent conduct of others or culpable participation in that conduct. See Mov. Br. at 19-20. Simply pleading the officer or director status of a particular defendant is clearly not sufficient. See, e.g., Rich v. Maidstone Financial, Inc., No. 98 CIV-2569 (DAB), 2002 WL 31867724, at *11 (S.D.N.Y. Dec. 20, 2002) ("pleading officer or director status alone is not enough"); Hemming v. Alfin Fragrances, Inc., 690 F. Supp. 239, 245 (S.D.N.Y. 1988) (a person's status as an officer, director or shareholder, absent more, is not enough to establish control liability). Plaintiffs have not provided any contrary authority in their opposition, nor have they pled anything more than Richards' bare status as the CFO.⁵ Consequently, all of plaintiffs' claims for liability in connection with statements not attributed to Richards must be dismissed.

⁵ Moreover, it is important to note that the operating function at Biopure over which Richards arguably did have some measure of control, the financial department, is not alleged to have acted improperly in any way. There is no allegation of any misstatement of revenues, income, expenses, cash balances or any other financial metric. Thus, to the extent that the plaintiffs would argue that officers of a public company are in a control relationship with the company, it is critical that the Court evaluate that control as it relates to specific statements that the plaintiffs allege were made by the company or other individuals within the company. As to these statements, which do not relate to financial issues, there are absolutely no specific allegations that support an inference that Richards had any measure of control.

CONCLUSION

For all of the foregoing reasons, Plaintiffs' Consolidated Complaint should be dismissed in its entirety, with prejudice.

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Respectfully submitted,

/s/ Christopher Robertson
Christopher F. Robertson (BBO # 642094)
SEYFARTH SHAW LLP
World Trade Center East
Two Seaport Lane, Suite 300
Boston, MA 02210-2028
Telephone: (617) 946-4800
Facsimile: (617) 946-4801

Attorney for Defendant Ronald F. Richards